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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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EXAMINER

18M1/0626

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ART UNIT	PAPER NUMBER
CABUTA, A	
1817	18

DATE MAILED: 06/26/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 3/5/97 ; 6/5/97

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-9,12-22,25-27,29,31-41 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 1-9,12-22,25-27,29,31-41 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☒ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

* U.S. GPO: 1996-404-496/40517

DETAILED ACTION

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1817.

2. Applicants arguments were received 3/5/97 and entered as Paper No. 16. Claims 1-9, 12-22, 25-27, 29, and 31-41 are pending.

Claim Rejections - 35 USC § 112

3. The prior rejection of claims 4, 8, 15, 21, 27, and 29 under 35 U.S.C. 112, first paragraph is withdrawn in view of applicants arguments.

4. The prior rejection of claims 1-3, 5-7, 9, 12-14, 16-20, 22, 25, 26, 31, and 32 under 35 U.S.C. 112, first paragraph directed to a lack of enablement to a composition and method of treatment of a herpesvirus having a mutation and in the gene encoding ICP 7 or 28, and said herpes virus encoding a foreign antigen is withdrawn in view of applicants arguments. However, applicants arguments are not sufficient to obviate a rejection of claims 1-3, 5-7, 9, 12-14, 16-20, 22, 25, 26, 31, and 32 under 35 USC 112, first paragraph for the reasons set forth below.

Claim Rejections - 35 USC § 112

5. Claims 1-3, 5-7, 9, 12-14, 16-20, 22, 25, 26, 31, 32, 33, 34, 36, 37-39, and 41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition and method of treatment of a herpesvirus having a mutation and in the gene encoding ICP 7 or 28, and said herpes virus encoding a foreign antigen does not reasonably provide enablement for broadly claiming a herpes virus having a mutation in one more genes encoding a protein essential for viral replication as broadly claimed. The specification does not

enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants argue they are entitled to the scope of the claims which encompass a herpesvirus that has a mutation in one or more genes encoding a protein essential for viral replication (see Paper No. 16, pages 6 and 7). Applicants arguments are not persuasive. While it would appear the specification discloses that the inactivation of two essential genes (ICP27 and ICP8) resulted in a functional mutant as argued by applicants said disclosure is no sufficient guidance for one skilled in the art to make and use the invention commensurate in scope with these claims.

Since:

1) the specification fails to provide little guidance (i.e. identity of the genes, or working examples) of mutants as ICP 8 and ICP 28 that have the properties as recited (i.e. renders

t the herpes virus defective, have the ability to effect an antibody shift, etc);

2) the specification discloses herpesvirus mutants that do not have the properties as claimed (e.g. failed to induce an antibody shift -see pages 50 and 51); and/or

3) proteins from herpesvirus essential for replication differ in structure

one skilled in the art would require undue experimentation to practice the broadly claimed invention.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 1-3, 5-7, 9, 12-14, 16-20, 22, 25, 26, 31, 32, 33, 34, 36, 37-39, and 41 are rejected under 35 U.S.C. 102(a) as being anticipated by Inglis et al. (WO 92/05263-Reference cited by Applicants in IDS Statement).

Inglis et al disclose a mutant virus which has a defect in gene essential for virus production (i.e. gH), whose genome includes genetic material including an immunogenic protein from a pathogen exogenous to said virus. Inglis et al. disclose said virus is a herpes simplex virus. Inglis et al disclose a vaccine comprising said virus (see pages 6, 17-25, 38 and 39). Inglis et al. disclose of vaccinating mice with the HSV-1 mutant in PBS, wherein said mutant has mutation in the gH gene. Inglis et al. further disclose said mutant expressing SIV-gp 120 (see pages 25-37). Inglis et al does not characterize the gH mutant as having the properties as recited (i.e. essential for viral replication). However, it is reasonable to conclude said mutant is essential for viral replication as claimed since the claimed invention as disclosed and set forth by Inglis et al are both drawn to a HSV-1 gH mutant. Inglis et al. does not characterize the method of vaccinating the animal for the intended use as recited. However, the intended use of the claimed invention (i.e. treatment of an immunomodulatory disease) carries no patentable weight.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 4, 8, 15, 21, 27, 35, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inglis et al. (WO 92/05263 Reference provided in Applicants' IDS).) and further view of McCarthy et al Journal of Virology 63(1):18-27 1989).

Claims 4, 8, 15, 21, 29, 35, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inglis et al. (WO 92/05263-1989-Reference provided in Applicants' IDS) and further view of Gao et al (Journal of Virology 63(12):5258-5267 1989-Reference provided in Applicants' IDS).

Inglis et al disclosure is set forth above. Inglis et al suggests using viral mutants that are inactivated for genes involved in viral genome replication for an immunogenic response (see pages 8-10; especially page 8; line 21 to page 9 line 12). Inglis et al teach the mutant virus can operate in the same way as an conventional killed virus or an attenuated virus (see page 8, lines 9-12). Inglis et al teach the invention can be applied to such virus as herpes viruses where the essential gene can be identified.

Inglis et al does not teach of using a ICP 8 or ICP 27 mutants as recited.

McCarthy et al teaches of HSV-1 ICP27 deletion mutants which were replication incompetent (see abstract).

Guo et al. teach of several mutant herpesvirus of the infected cell protein 8 (ICP 8) which lack the ability to replicate and bind (see abstract, page 5259, Figure 5, and Table 4) . Guo et al. Describes a mutant d301 from HSV which is replication defective.

While Inglis et al does not teach of using a ICP 8 or ICP 27 mutants as recited, since Inglis et al. suggests viral mutants that are inactivated for genes involved in viral genome replication for an immunogenic response and vaccination it would have obvious to one of ordinary skill in the art that the ICP 27 mutant as set forth McCarthy et al or ICP 8 mutant as set forth by Guo et al would have been useful for vaccination.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Anthony C. Caputa, whose telephone number is (703)-308-3995. The examiner can be reached on Monday-Thursday from 8:30 AM-6:00 PM. The examiner can be reached on alternate Fridays. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703)-308-0196.

Papers related to this application may be submitted to Art Unit 1817 by facsimile transmission. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The Fax number is (703)-308-4242.

Anthony C. Caputa, Ph.D.
June 25, 1997

A. C.

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PRIMARY EXAMINER
GROUP 1800